Department of Defense
Department of the Navy
Human Research Protection Program

Directions for Submitting an Assurance Application for the Protection of Human Research Subjects

Who must submit an Assurance Application?

1. Institutions engaged* in DoD-DON-supported research with human subjects must submit an Assurance application for a new assurance or to renew or update an already-approved assurance.

> **An institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes.* [32 CFR 219.102(d),(f) and OHRP policy January 1999]

2. The Assurance application is used when:

a. The institution applying for the Assurance will be using its own Institutional Review Board (IRB(s)), or

b. The institution applying for the Assurance will be using its own IRB(s) and may rely on an IRB of another institution for research review, or

c. The institution applying for the Assurance does not have its own IRB and is relying on another institution's IRB for research review.

Step-by-Step Directions

Note: Institutions must have written Standard Operating Procedures (SOPs) describing how they meet and implement each item in this Assurance. The Assurance is not a substitute for institutional policies and SOPs.

1. Fill in the required information

a. The first page is to be on institutional letterhead

b. **Institution Information:**

1) Check the appropriate box for new, renewal, or update of assurance. For renewal or update, provide the current DOD N Assurance number.

2) Insert the official institution's name and address, including any groups, sites, activities, and/or entities under the jurisdiction of the institution named in the assurance.

3) When the institution holds a Federalwide Assurance (FWA) from the Department of Health and Human Services, Office of Human Research Protections (DHHS OHRP), provide the FWA number. See http://www.hhs.gov/ohrp/assurances/assurances_index.html.

c. **Part 1**: **Ethical Principles, Applicability, and Institutional Policies:** Use this section to verify that your institution has a copy of and/or access to, via electronic files or websites, the federal regulations, instructions, and other guidance cited in this document.

d. **Part 2**: **Designation of Institutional Review Boards (IRB(s)):** Use this section to designate one or more IRBs that review human subject research for the institution. Institutions proposing to rely on the IRB(s) of another institution should ensure that the arrangement is acceptable. Institutions may contact DON HRPP to discuss proposed arrangements.

1) Institution using its own IRB(s): Complete Section I and skip to Part 3, Institutional Promise.

2) Institution using its own IRB(s) and relying on another institution's IRB for research review:

a) Complete Section I

b) Section III – Signatures: The Institutional Signatory Official and the IRB Chair(s) of institution with the reviewing IRB **must sign** this section.

c) Complete Part 3, Institutional Promise.

d) Complete and attach the appropriate Joint Research Review Agreement (JRRA). See Assurance application, Part 1, section III.A.12 and section III.A.13 for details.

3) Institution does not have own IRB and relies on another institution's IRB:

a) Complete Section II

b) Section III – Signatures: The Institutional Signatory Official and the IRB Chair(s) of institution with the reviewing IRB **must sign** this section.

c) Complete Part 3, Institutional Promise.

d) Complete and attach the appropriate Joint Research Review Agreement. See Assurance application, Part 1, section III.A.12 and section III.A.13 for details.

e. **Part 3**: **Institutional Promise:** Use this section to identify the Institutional Signatory Official**, IRB Chair(s), and Primary Contact for Human Research Protection, each of whom must complete the required education and training ***prior*** to submitting the Assurance to the DON HRPP.

** The Institutional Signatory Official must be a senior-level institutional official authorized to represent the institution, and any other institutions named in the Assurance, and to assume on behalf of the institution, the obligations imposed by federal regulations, DoD, and DON requirements for the protection of human subjects.

[Note: The requirement that the Institutional Signatory Official be a senior executive is intended to encourage institutions, at their highest levels, to foster a culture of integrity that supports the ethical conduct of human subject research. The Institutional Signatory Official also must have the authority to take administrative or legal action needed to enforce human-research protection standards.]

In most cases, the Commander, Commanding Officer, Officer-in-Charge, or Head of Activities serves as the Institutional Signatory Official.

All signatures and dates in Part 2 (if applicable) and Part 3 must be handwritten if an original copy is submitted. Signed and dated originals may be scanned and submitted electronically.

1) IRB Chair(s) and IRB members are not permitted to serve as the Institutional Signatory Official.

2) Required Training for DOD N Assurance

a) The Institutional Signatory Official of the Assurance must complete both DON HRPP training requirements **and** Module 1 of the Office for Human Research Protections (OHRP) "Human Subject Assurance Online Training" available at OHRP's web-site (http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp).

The Executive Officer or the individual who acts for the Commander, Commanding Officer, or Head of Activity during their absence, also must complete the training.

b) The Institution's IRB Chair(s), IRB Vice Chair(s), and Primary Contact for Human Research Protection must complete DON HRPP training requirements **and** all three modules available at the same OHRP website.

c) Submit copies of the completed training certificates with Part 4 – Institution's Supporting Documentation.

f. **Part 4**: **Institution's Supporting Documentation:** Complete the table with information about each of the items being submitted to support the Assurance application.

1) **Do not** include federal regulations, instructions, or guidance already cited in this Assurance Application.

2) Provide the documentation either as an original, scanned electronic transmission, or by emailing a link to a website that contains the documentation.

3) The documentation requirements may be met by SOPs, instructions, and/or guidelines that describe how the institution and IRB review, conduct, and oversee research with human subjects. These documents should describe all the specific requirements listed in Part 1, Sections III.A and III.B of this assurance application. If appropriate, reference an existing policy that the institution follows, (i.e., NIH Policy, DON HRPP policy).

4) Complete the table in the Assurance application using the chart at the end of these directions to determine which documents to submit.

2. Submit the Assurance to DON HRPP

a. Institutions may submit a DRAFT Assurance application to the DON HRPP for pre-review and feedback prior to submitting the fully signed Assurance. Submitting a draft, particularly when an institution proposes to rely on another institution's IRB for reviewing research, will facilitate discussion, negotiation, and decision about the appropriateness of the proposed arrangement.

b. Institutions with their own IRB(s) and that will be relying on another institution's IRB for research review OR institutions that do not have their own IRB and will be relying on another institution's IRB should submit their Assurance application to the DON HRPP as follows:

1) The institution applying for the Assurance should sign the Assurance application first and then send the signed application to the institution with the reviewing IRB for their signature.

2) The institution with the reviewing IRB should sign and forward the Assurance to the DON HRPP. Alternatively, they may return the signed application to the institution applying for the Assurance who will submit it to the DON HRPP.

c. Send the application to:

Department of the Navy
Human Research Protection Program
Bureau of Medicine and Surgery (Code M00R)
2300 E Street NW
Washington, D.C. 20372-5300
FAX: 202-762-0976
Email: humanresearch@us.med.navy.mil

Review of the Assurance Application

The DON HRPP Assurance Approval Authority will review the Assurance. An application for a new assurance may be approved, returned for modifications for approval, limited in scope, or disapproved. An application for renewal or update of an Assurance may be approved, returned for modifications, restricted, suspended, or disapproved. The Institutional Signatory Official will be notified of the decision.

Once the Assurance is approved, the DON HRPP will provide to the institution a DOD N Assurance number. The DON HRPP will send copies of the approved Assurance to the signatories (Institutional Signatory Official, IRB Chair(s), and the Primary Contact – Human Research Protections and the Institutional Signatory Official and IRB Chair(s) of any institution whose IRB(s) serves as a reviewing IRB).

Institutional Responsibilities After Approval

Institutions are responsible for promptly submitting updated assurance information when there are changes to:

1. The Institutional Signatory Official
2. IRB Chair(s)
3. IRB membership (only its own IRB(s))
4. Human Research Protection Primary Contact
5. The supporting documents attached to the Assurance.

Institution will submit an application a DOD Navy Assurance renewal 60 days prior to the expiration date, even if no changes have occurred, in order to maintain an active, approved Assurance. If an institution's Assurance approval expires prior to renewal, all research must stop, except when halting research would endanger subjects. There is no grace period.

Failure to maintain a current approved DOD Navy Assurance may result in restriction, suspension, or termination of the institution's Assurance of Protection for Human Subjects and restriction, suspension, or termination of the institution's human subject research.

Record Keeping

Institutions must maintain the DOD Navy Assurance and supporting documents to be available for review by DON HRPP.

Part 4 – Supporting Documents

	Institution with own IRB	Institution does not have own IRB; relying on another reviewing IRB	Institution with own IRB and relying on another reviewing IRB
1. Current Training Certificates			
a. Institutional Signatory Official	X	X	X
b. IRB Chair(s)	X	Not applicable	X (Only its own)
c. Human Research Protection Primary Contact	X	X	X
d. Executive Officer	X	X	X
2. Institutional Policies and Procedures			
a. Organizational Chart showing communication – IRB, HRP POC and ISO	X	X	X
b. Policy or Instruction for monitoring and overseeing research conducted at this institution.	X	X	X
c. Education Policy for research ethics training, including human subject protection	X	X	X
d. Guidelines for investigators	X	X	X
e. Conflict of Interest policy	X	X	X
f. Policy and procedures for handling allegations of non-compliance with human research protections	X	X	X
g. Policy and procedures for handling allegations of research misconduct	X	X	X
h. IRB membership list(s)	X	*	X (Only for its own IRB)
i. Joint Research Review Agreement /Other agreement	Not applicable	X **	X **

* An institution submitting an Assurance that relies on an IRB(s) of another institution for research review is not required to submit the IRB membership list(s) for those IRB(s). The DON HRPP will verify this information.
** Required when an institution submitting an Assurance relies on IRB(s) of other institution(s). The JRRA/Other agreement describes the relationship between the institution submitting the Assurance and the institution with the reviewing IRB.